IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
ANDERSON/GREENWOOD DIVISION

Phillip Lamar West, Individually, and Karen Austin, Individually, and as Husband and Wife Plaintiffs, -versus- Sorin Group Deutschland GMBH and Sorin Group USA, Inc. Defendants.	)	Civil Action No.: 8:16-cv-02688-MGL **AMENDED ANSWER AND AFFIRMATIVE DEFENSES ON BEHALF OF DEFENDANT SORIN GROUP DEUTSCHLAND GMBH AND DEFENDANT SORIN GROUP USA, INC.**

Defendants Sorin Group USA, Inc. ("Sorin USA"), and Sorin Group Deutschland GMBH ("Sorin Deutschland") (collectively, "Defendants"), for their answer and affirmative defenses to the First Amended Complaint ("Complaint") of Plaintiffs Phillip Lamar West and Karen Austin ("Plaintiffs"), respond as follows. Each and every allegation not expressly admitted herein is denied.

FOR A FIRST DEFENSE
(General Denial)

PARTIES TO THIS ACTION

1. Defendants lack sufficient information or knowledge to form a belief as to the truth or falsity of the allegations in Paragraph 1 of the Complaint and, therefore, deny them.

2. Defendants admit that Sorin Deutschland is a foreign for-profit company headquartered in Munich, Germany. Defendants also admit that Sorin Deutschland is the registered manufacturer of and designed and marketed the 3T Heater-Cooler System. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 2 of the Complaint.

3. Defendants admit that Sorin USA has a principal place of business in Arvada, Colorado, and markets and distributes the 3T System in the United States. Defendants also admit that they are wholly owned subsidiaries of LivaNova PLC, which is a holding company in the fields of Cardiac Surgery, Neuromodulation, and Cardiac Rhythm Management. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 3 of the Complaint.

JURISDICTION AND VENUE

4. Defendants admit that they are subject to personal jurisdiction in this District, for purposes of this case only. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 4 of the Complaint.

5. Defendants admit that this Court has subject matter jurisdiction over this action, for purposes of this action only.

6. Defendants admit that venue in the District of South Carolina is proper and that they are subject to Personal Jurisdiction in the District of South Carolina, for purposes of this action only. Defendants deny the remaining allegations in Paragraph 6 of the Complaint.

FACTUAL ALLEGATIONS

7. Defendants restate their answers to Paragraphs 1–6 above.

8. Defendants admit that Sorin USA markets and sells the Sorin 3T System in the United States. Except as expressly admitted, Defendants deny the remaining allegations.

9. Defendants admit that prior to May 5, 2014, Sorin USA marketed and distributed the Sorin 3T System in the United States. Defendants also admit that Sorin Deutschland was the registered manufacturer of the 3T System. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 9 of the Complaint.

10. Defendants admit that a 510(k) Premarket Notification was submitted for the 3T System, the 3T System is a Class II device, and its Intended Use is "to provide temperature-

controlled water to heat exchanger devices (cardiopulmonary bypass heat exchangers, cardioplegia heat exchangers, and thermal regulating blankets) to warm or cool a patient during cardiopulmonary bypass procedures lasting six (6) hours or less." The remaining allegations in paragraph 10 of this Complaint allege conclusions of law to which no response is required, but, to the extent a response is required, Defendants deny the same. Defendants deny the remaining allegations in paragraph 10 of the Complaint and in the footnote to Paragraph 10.

11. Defendants admit that before commercial distribution in the United States of the 3T System, Sorin Deutschland submitted a Traditional 510(k) Premarket Notification for the Stockert Heater-Cooler System 3T and that the United States Food and Drug Administration ("FDA") cleared the 3T System to market by letter dated June 6, 2006. The contents of the Premarket Notification and the clearance letter speak for themselves, and Defendants deny the characterization of these documents and footnotes contained in Paragraph 11 of the Complaint. All remaining allegations in Paragraph 11 of the Complaint allege conclusions of law to which no response is required, but, to the extent a response is required, Defendants deny the same.

12. Defendants admit that the FDA cleared the 3T System to market by letter dated June 6, 2006. The contents of the clearance letter speak for themselves, and Defendants deny the characterization of this document contained in Paragraph 12 of the Complaint. All remaining allegations in Paragraph 12 of the Complaint allege conclusions of law to which no response is required, but, to the extent a response is required, Defendants deny the same.

13. Defendants lack sufficient information or knowledge to form a belief as to the truth or falsity of the allegations in Paragraph 13 of the Complaint and, therefore, deny them.

14. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations and footnotes in Paragraph 14 of the Complaint and, therefore, deny them.

15. Defendants admit only that the first sentence of Paragraph 15 of the Complaint partially quotes from a Centers for Disease Control ("CDC") website http://www.cdc.gov/HAI/organisms/mycobacterium.html as it existed on September 1, 2016. Defendants deny any characterization of this website, which speaks for itself, and deny all remaining allegations and footnotes in Paragraph 15 of the Complaint.

16. Defendants lack sufficient information or knowledge to form a belief as to the truth or falsity of the allegations in Paragraph 16 of the Complaint and, therefore, deny them.

17. Defendants deny that the first sentence of Paragraph 17 of the Complaint accurately quotes the CDC website http://www.cdc.gov/HAI/organisms/mycobacterium.html as it existed on July 29, 2016. Defendants admit only that the words within the quotation marks in the second sentence of Paragraph 17 were listed on the CDC website as of July 29, 2016, as "Other signs of *M. abscessus* infection." Defendants deny the characterization of this website, which speaks for itself, and deny all remaining allegations and footnotes in Paragraph 17 of the Complaint.

18. Defendants deny that the statements in Paragraph 18 of the Complaint accurately set forth what was stated on the CDC website http://www.cdc.gov/HAI/organisms/mycobacterium.html as of July 17, 2016. Defendants lack sufficient information or knowledge to form a belief as to the truth or falsity of the remaining allegations and footnotes in Paragraph 18 of the Complaint and, therefore, deny them.

19. Defendants admit only that the allegations in Paragraph 19 of the Complaint accurately list certain treatments identified on the CDC website http://www.cdc.gov/HAI/organisms/mycobacterium.html as of July 17, 2016. Defendants deny the characterization of this website, which speaks for itself, and deny all remaining allegations and footnotes in Paragraph 19 of the Complaint.

20. Defendants lack sufficient information or knowledge to form a belief as to the truth or falsity of the allegations and footnotes in Paragraph 20 of the Complaint and, therefore, deny them.

21. Defendants admit only that Paragraph 21 of the Complaint partially quotes from a document dated July 15, 2015, and posted by the FDA, which speaks for itself. Defendants deny Plaintiffs' characterization of the posted document and deny the remaining allegations and footnotes in Paragraph 21 of the Complaint.

22. Defendants admit that a June 15, 2015 Field Safety Notice was signed by Christian Peis, Director of Quality Assurance for Sorin Deutschland, and that the contents of that document speak for themselves. Defendants also admit that an August 6, 2015 Update to the Field Safety Notice was signed by Christian Peis, and that the contents of that document speak for themselves. Defendants deny Plaintiffs' characterization of the June 15, 2015 Field Safety Notice, August 6, 2015 Update to the Field Safety Notice, and the related footnote and deny the remaining allegations of Paragraph 22 of the Complaint.

23. Defendants admit that a June 15, 2015 Field Safety Notice and August 6, 2015 Update to the Field Safety Notice was signed by Christian Peis, Director of Quality Assurance for Sorin Deutschland, and that the contents of that document speak for themselves. Defendants

deny Plaintiffs' characterization of the June 15, 2015 Field Safety Notice and the related footnote, and deny the remaining allegations of Paragraph 23 of the Complaint.

24. Defendants deny the allegations in Paragraph 24 of the Complaint.

25. Defendants admit that the FDA issued a December 29, 2015 Warning Letter regarding inspections conducted at Sorin USA and Sorin Deutschland facilities, and that the contents of the December 29, 2015 letter speak for themselves. Defendants deny Plaintiffs' characterization of the December 29, 2015 Warning Letter, and deny the remaining allegations and footnote in Paragraph 25 of the Complaint.

26. Defendants admit that the FDA issued a December 29, 2015 Warning Letter regarding inspections conducted at Sorin USA and Sorin Deutschland facilities, and that the contents of the December 29, 2015 letter speak for themselves. Defendants deny Plaintiffs' characterization of the December 29, 2015 Warning Letter, and deny the remaining allegations in Paragraph 26 of the Complaint.

27. Defendants deny the allegations in Paragraphs 27–36 of the Complaint.

FACTS SPECIFIC TO THIS CASE

28. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 37–43 of the Complaint and, therefore, deny them.

COUNT I - NEGLIGENCE

29. In response to Paragraph 44 of the Complaint, Defendants restates its answers to Paragraphs 1–43 above.

30. Paragraph 45 of the Complaint contains conclusions of law to which no response is required, but, to the extent a response is required, Defendants deny the same. Defendants deny all remaining allegations in Paragraph 45 of the Complaint.

31. Defendants deny the allegations in Paragraph 46 of the Complaint.

32. Paragraph 47 of the Complaint contains conclusions of law to which no response is required, but, to the extent a response is required, Defendants deny the same. Defendants deny all remaining allegations in Paragraph 47 of the Complaint.

33. Defendants deny the allegations in Paragraph 48 of the Complaint.

34. Paragraph 49 of the Complaint contains conclusions of law to which no response is required, but to the extent a response is required, Defendants deny the same. Defendants deny all remaining allegations in Paragraph 49 of the Complaint.

35. Defendants deny the allegations in Paragraph 50 of the Complaint.

36. Defendants deny the allegations in Paragraph 51 of the Complaint.

37. Defendants deny the allegations in Paragraph 52 of the Complaint.

COUNT II - STRICT PRODUCTS LIABILITY

38. In response to Paragraph 53 of the Complaint, Defendants restate their answers to Paragraphs 1–52 above.

39. Paragraph 54 of the Complaint contains conclusions of law to which no response is required, but to the extent a response is required, Defendants deny the same. Defendants deny all remaining allegations in Paragraph 54 of the Complaint.

40. Defendants deny the allegations in Paragraph 55 of the Complaint.

41. Defendants deny the allegations in Paragraph 56 of the Complaint.

COUNT III - BREACH OF EXPRESS WARRANTY

42. In response to Paragraph 57 of the Complaint, Defendants restate their answers to Paragraphs 1–56 above.

43. Defendants admit that their labeling contains certain representations about the 3T System and its intended use. Defendants also admit that certain implied warranties may operate as a matter of law, and aver that these warranties were met, as the 3T System was of

merchantable quality and fit for the ordinary purposes and uses for which it was sold. Except as stated, Defendants deny any express representations to the Plaintiffs, and deny all remaining allegations of Paragraph 58 of the Complaint.

44. Defendants admit only that health care providers may rely on certain representations when selecting a given product; however, Defendants lack sufficient information or knowledge about any specific representations on which Plaintiff West's health care providers may have relied, and deny any express representations to the Plaintiffs. Defendants deny all remaining allegations in Paragraph 59 of the Complaint.

45. Defendants deny the allegations in Paragraph 60 of the Complaint.

46. Defendants deny the allegations in Paragraph 61 of the Complaint.

COUNT IV - BREACH OF IMPLIED WARRANTIES

47. In response to Paragraph 62 of the Complaint, Defendants restate their answers to Paragraphs 1–61 above.

48. Defendants admit that their labeling contains certain representations about the 3T System and its intended use. Defendants also admit that certain implied warranties may operate as a matter of law, and aver that these warranties were met, as the 3T System was of merchantable quality and fit for the ordinary purposes and uses for which it was sold. Except as stated, Defendants deny any express representations to the Plaintiffs, and deny all remaining allegations of Paragraph 63 of the Complaint.

49. Defendants lack sufficient information or knowledge to form a belief as to the truth or falsity of the allegations in Paragraph 64 of the Complaint and, therefore, deny all allegations in Paragraph 64 of the Complaint.

50. Defendants deny the allegations in Paragraph 65 of the Complaint.

51. Defendants deny the allegations in Paragraph 66 of the Complaint.

52. Defendants deny the allegations in Paragraph 67 of the Complaint.

53. Defendants deny the allegations in Paragraph 68 of the Complaint.

COUNT V - NEGLIGENT MISREPRESENTATION

54. In response to Paragraph 69 of the Complaint, Defendants restate their answers to Paragraphs 1–68 above.

55. Defendants deny the allegations in Paragraph 70 of the Complaint.

56. Defendants deny the allegations in Paragraph 71 of the Complaint.

57. Defendants deny the allegations in Paragraph 72 of the Complaint.

58. Defendants deny the allegations in Paragraph 73 of the Complaint.

59. Defendants deny the allegations in Paragraph 74 of the Complaint.

60. Defendants deny the allegations in Paragraph 75 of the Complaint.

COUNT VI - MISREPRESENTATION BY OMISSION

61. In response to Paragraph 76 of the Complaint, Defendants restate their answers to Paragraphs 1–75 above.

62. Defendants deny the allegations in Paragraph 77 of the Complaint.

63. Defendants deny the allegations in Paragraph 78 of the Complaint.

64. Defendants deny the allegations in Paragraph 79 of the Complaint.

65. Defendants deny the allegations in Paragraph 80 of the Complaint.

66. Defendants deny the allegations in Paragraph 81 of the Complaint.

67. Defendants deny the allegations in Paragraph 82 of the Complaint.

68. Defendants deny the allegations in Paragraph 83 of the Complaint.

COUNT VII - VIOLATION OF THE SOUTH CAROLINA UNFAIR TRADE PRACTICES ACT

69. In response to Paragraph 84 of the Complaint, Defendants restate their answers to Paragraphs 1–83 above.

70. Defendants admit that Paragraph 85 of the Complaint accurately quotes from the South Carolina Unfair Trade Practices Act, S.C. CODE ANN. § 39-5-20.

71. Defendants deny the allegations in Paragraph 86 of the Complaint.

72. Defendants deny the allegations in Paragraph 87 of the Complaint.

73. Defendants deny the allegations in Paragraph 88 of the Complaint.

74. Defendants deny the allegations in Paragraph 89 of the Complaint.

COUNT VIII - LOSS OF CONSORTIUM

75. In response to Paragraph 90 of the Complaint, Defendants restate their answers to Paragraphs 1–89 above.

76. Defendants deny the allegations in Paragraph 91 of the Complaint.

77. Defendants deny the allegations in Paragraph 92 of the Complaint.

PUNITIVE DAMAGES

78. In response to Paragraph 93 of the Complaint, Defendants restate their answers to Paragraphs 1–92 above.

79. Defendants deny the allegations in Paragraph 94 of the Complaint.

ACTUAL DAMAGES

80. In response to Paragraph 95 of the Complaint, Defendants restate their answers to Paragraphs 1–94 above.

81. Defendants deny the allegations in Paragraph 96 of the Complaint and each subpart.

PRAYERS FOR RELIEF

89. Defendants assert that the Paragraphs 97–98 in Plaintiffs' Complaint under "Prayers for Relief" do not require a response. To the extent that they do require a response, Defendants deny them, and deny that Plaintiffs are entitled to any relief whatsoever, including, without limitation, the relief requested in the Prayers for Relief.

FOR A SECOND DEFENSE
(Failure to state a claim)

90. The Complaint, and each claim against Defendants contained therein, fails to state a claim upon which relief can be granted.

FOR A THIRD DEFENSE
(Spoliation)

91. Plaintiffs' Complaint is barred, in whole or in part, to the extent there is spoliation of evidence.

FOR A FOURTH DEFENSE
(Preemption)

92. Plaintiffs' claims for strict liability design defect, strict liability manufacturing defect, and negligence are barred or preempted by federal law pursuant to the Supremacy Clause of the United States Constitution and the laws of the United States.

FOR A FIFTH DEFENSE
(Modification, Alteration, Change)

93. Plaintiffs' claims are barred, to the extent that the product at issue in this litigation was modified, altered, or changed from the condition in which it was sold, which modification, alteration, or change caused or contributed to cause Plaintiffs' alleged damages.

FOR A SIXTH DEFENSE
(No Alternative Feasible/Reasonable Design)

94. Plaintiffs' claims are barred because at the time the product at issue in this litigation left the manufacturer's control, a practical and technically feasible alternative design or formulation was not available that would have prevented the harm for which Plaintiffs seek to recover damages without substantially impairing the reasonably anticipated or intended function of the product.

FOR A SEVENTH DEFENSE
(No Design Defect)

95. Plaintiffs' damages, if any, were caused by inherent characteristics of the product that are generic aspects of the product that cannot be eliminated without substantially compromising the product's usefulness or desirability.

FOR AN EIGHTH DEFENSE
(Benefit/Risk Not Met)

96. Plaintiffs' claims are barred because the benefits of the product at issue in this litigation outweigh the risk of danger or harm, if any, of the product.

FOR A NINTH DEFENSE
(State of the Art)

97. Plaintiffs' claims are barred, because Defendants' actions conformed to the state of the art of reasonably available scientific and technological knowledge at all times relevant to this lawsuit. The product at issue in this litigation was in conformity with the generally recognized state of the art applicable to the safety of the product at the time the product was designed, manufactured, packaged, or labeled.

FOR A TENTH DEFENSE
(Compliance with Applicable Law)

98. Plaintiffs' Complaint is barred, because at the time the product at issue in this litigation left the control of the manufacturer, it complied with applicable codes, standards, regulations, and specifications established, adopted, promulgated, or approved by the United States and/or by the State of South Carolina.

FOR AN ELEVENTH DEFENSE
(*Noerr-Pennington* Doctrine)

99. Any communications and/or actions between Defendants and the FDA and/or any governmental agency or entity are constitutionally protected under the *Noerr-Pennington* doctrine and the First Amendment to the United States Constitution.

FOR A TWELFTH DEFENSE
(Comparative Negligence)

100. The injuries and damages claimed by Plaintiffs may have resulted from Plaintiff West's and/or Plaintiffs' own conduct, such that Plaintiffs' claims may be barred by the comparative negligence, fault, responsibility or causation attributed to Plaintiffs. Thus, Plaintiffs' claims may be dismissed, reduced, offset, or barred in accordance with the principles of comparative negligence. Plaintiffs' recovery of damages, if any exist, may be reduced or barred by the comparative negligence and/or fault of Plaintiffs and/or other persons, including responsible non-parties, pursuant to South Carolina law.

FOR A THIRTEENTH DEFENSE
(Acts of Third Parties)

101. If Plaintiffs sustained damages by reason of the matters alleged in the Complaint, which is denied, then those damages were caused solely by or contributed to by the acts or fault

of third parties and were not caused or contributed to by any acts or fault of Defendants, their officers, agents, contractors, servants, employees, or others for whom they were responsible.

FOR A FOURTEENTH DEFENSE
(Failure to Heed Warnings)

102. Plaintiffs' claims may be barred because any injuries or damages sustained by Plaintiffs may have been directly and proximately caused by the failure of Plaintiff West to heed warnings and instructions and/or Plaintiff West's failure to follow the reasonable advice of his health care providers.

FOR A FIFTEENTH DEFENSE
(Failure to Mitigate Damages)

103. Plaintiffs' claims may be barred because if Plaintiffs sustained damages as alleged in the Complaint, which is denied, Plaintiffs may have failed to mitigate those damages.

FOR A SIXTEENTH DEFENSE
(Idiosyncratic Reactions)

104. Plaintiffs' claims are barred to the extent the injuries alleged in the Complaint resulted from pre-existing and/or unrelated medical conditions and/or idiosyncratic reactions to the product at issue and not from any act or omission by Defendants or by any defect in the product at issue. Plaintiffs' claims are further barred because the damages and injuries alleged, if any, were caused or enhanced by a pre-existing medical or psychiatric condition of Plaintiff West that were not related to the distribution or sale of the product at issue.

FOR A SEVENTEENTH DEFENSE
(Intervening/Superseding Acts)

105. Plaintiffs' claims are barred to the extent the injuries alleged in the Complaint resulted from unforeseeable, independent, intervening, or superseding events beyond the control, and unrelated to the conduct of Defendants, including but not limited to pre-existing and/or

unrelated medical conditions, the acts or omissions of persons other than Defendants and over whom Defendants had no control, and/or other causes unknown at this time. The actions and omissions of Defendants, if any, were superseded by such unforeseeable, independent, intervening, and superseding events.

FOR AN EIGHTEENTH DEFENSE
(Failure to Provide Timely Notice)

106. Plaintiffs' breach of warranty claims are barred because Plaintiffs do not have standing to assert the claims. Alternatively, to the extent Plaintiffs have standing, their breach of warranty claims are barred because Plaintiffs failed to satisfy all conditions precedent or subsequent to the enforcement of such warranty and Plaintiffs failed to give timely notice of any alleged breach of warranty, whether express or implied, to Defendants. Plaintiffs also did not reasonably rely upon any alleged warranty, whether express or implied. Any warranty, whether express or implied, was adequately disclaimed, excluded, or modified.

FOR A NINETEENTH DEFENSE
(Right to Set-Off)

107. To the extent that any claims stated in the Complaint have been settled, compromised, or otherwise discharged, a set off is due.

FOR A TWENTIETH DEFENSE
(Limitation on Damages)

108. Plaintiffs' alleged damages are barred, reduced and/or limited pursuant to any other applicable limitations of awards, prejudgment interest, caps on recovery, and setoffs permitted by law, including, but not limited to South Carolina law regarding non-economic loss or injury, and applicable South Carolina law related to amounts paid or provided by collateral sources.

FOR A TWENTY-FIRST DEFENSE
(Joint and Several Liability)

109. To the extent Defendants are found liable in part, Defendants avail themselves of the relief and remedies available to them for joint and several liability under South Carolina law. S.C. CODE ANN. 15-38-15 (2005).

FOR A TWENTY-SECOND DEFENSE
(Not Unreasonably Dangerous)

110. The 3T System allegedly at issue in this action was not in an unreasonably dangerous condition at the time it left the possession of Defendants.

FOR A TWENTY-THIRD DEFENSE
(Comment K)

111. Plaintiffs' claims are subject to the limitations set forth in Restatement (Second) of Torts, Section 402A, including Comment K, adopted into law by S.C. CODE ANN. § 15-73-30.

FOR A TWENTY-FOURTH DEFENSE
(Restatement (Third) of Torts)

112. Defendants adopt and rely upon all defenses provided in sections 2, 4, and 6 of the Restatement (Third) of Torts: Products Liability.

FOR A TWENTY-FIFTH DEFENSE
(Reservation of Constitutional Protections)

113. Defendants adopt and rely upon all provisions and defenses afforded them under the United States and South Carolina Constitutions.

FOR A TWENTY-SIXTH DEFENSE
(Reservation of Defenses under Applicable Law)

114. Defendants adopt and rely upon all provisions and defenses afforded them under South Carolina's product liability law, including S.C. CODE ANN. § 15-73-10, *et seq.*, the Uniform Commercial Code as enacted in South Carolina, and case law in interpretation thereof.

FOR A TWENTY-SEVENTH DEFENSE
(No Punitive Damages Generally)

115. To the extent Plaintiffs seek exemplary or punitive damages, Defendants specifically incorporate by reference all standards and/or limitations regarding the determination and enforceability of punitive damage awards that arise in the decisions of *BMW of North Am. v. Gore*, 517 U.S. 559 (1996), *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001), and *State Farm Mut. Auto. Ins. Co. v. Campbell* 123 S. Ct. 1513, 1519, 1521 (2003).

FOR A TWENTY-EIGHTH DEFENSE
(No Punitive Damages for Strict Liability/Breach of Warranty)

116. To the extent Plaintiffs seek exemplary or punitive damages, any such claims based solely on a cause of action for strict liability or breach of warranty are barred by South Carolina law.

FOR A TWENTY-NINTH DEFENSE
(No Waiver of Defenses)

117. Defendants have not knowingly or intentionally waived any applicable defenses and reserve the right to assert and rely on any other applicable defenses as may become available or apparent during discovery proceedings. Defendants further reserve the right to delete defenses that Defendants determine are no longer applicable, and to amend this Answer or these defenses accordingly.

FOR A THIRTIETH DEFENSE
(No Unfair or Deceptive Act)

118. Plaintiffs' cause of action purportedly based on the South Carolina Unfair Trade Practices Act is barred because Defendants have not engaged in any unfair or deceptive acts.

FOR A THIRTY-FIRST DEFENSE
(Regulatory Exemption)

119. Plaintiffs' cause of action purportedly based on the South Carolina Unfair Trade Practices Act is barred because any and all acts of Defendants allegedly giving rise to such cause of action are permitted and regulated by the FDA.

FOR A THIRTY-SECOND DEFENSE
(No Actual Damages under UTPA)

120. Plaintiffs' cause of action purportedly based on the South Carolina Unfair Trade Practices Act is barred because Plaintiffs have failed to show that they suffered actual, ascertainable damages as a result of the acts of Defendants that are alleged to constitute an unfair trade practice, which acts are denied.

FOR A THIRTY-THIRD DEFENSE
(No Act Affects Public Interest)

121. Plaintiffs' cause of action purportedly based on the South Carolina Unfair Trade Practices Act is barred because any conduct of Defendants allegedly constituting an unfair trade practice, which is specifically denied by Defendants, does not adversely affect the public interest as construed by the courts of South Carolina.

FOR A THIRTY-FOURTH DEFENSE
(No Proximate Cause)

122. Plaintiffs' claims fail because their alleged claims and damages were not proximately caused by any act or omission of Defendants.

FOR A THIRTY-FIFTH DEFENSE
(Reservation of All Affirmative Defenses)

123. Defendants reserve all other affirmative defenses under Fed. R. Civ. P. 8(c) and any other defenses at law or in equity, that may exist now or in the future based on discovery and further factual investigation in this case.

JURY DEMAND

Defendants hereby demand a trial by jury.

WHEREFORE, Defendants request that judgment be entered in their favor, with costs and fees as permitted by law, and against Plaintiffs with respect to their claims asserted in this suit, and for any other relief to which Defendants have shown themselves justly entitled.

Respectfully submitted this 27th day of October, 2016.

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